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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/600,361

06/20/2003

Jean-Marie Andrieu

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EXAMINER

LE, EMILY M

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

10/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/600,361

Applicant(s)

ANDRIEU ET AL.

Examiner

Emily Le

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 08, 2007+August 16, 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43,44,46 and 52-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-44, 46 and 52-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 16, 2007 has been entered. In view of the RCE amendment, Applicant's after final submission has also been entered. Since it is noted that different amendment to the claims were submitted with both the RCE and after final filings, the examination will be based on the latest set of claims, those filed August 16, 2007.

Status of Claims

2. Claims 1-42, 45 and 47-51 are cancelled. Claims 43-44, 46 and 52-56 are pending and under examination.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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4. Claims 43 and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Belardelli et al.¹

The claims are directed to a composition comprising dendritic cells pulsed with an inactivated human immunodeficiency virus (HIV), wherein the dendritic cells are obtained from a monocyte by plastic-adherence followed by culture with GM-CSF and IL-4 and a pharmaceutically acceptable carrier, and wherein the virus is chemically inactivated by 2,2'-dithiopyridine. Claim 46, which depends on claim 43, requires the dendritic cells to be autologous.

Belardelli et al. teaches composition comprising dendritic cells pulsed with an inactivated human immunodeficiency virus (HIV) and a pharmaceutically acceptable carrier. [Paragraphs 0066-0067 and 0071, in particular.] The dendritic cells used by Belardelli et al. were obtained from a monocyte by plastic-adherence followed by culture with GM-CSF and IL-4. Belardelli et al. uses AT-2, 2,2'-dithiopyridine, to chemically inactivate the virus. And Belardelli et al. uses autologous dendritic cells.

In summation, Belardelli et al. teaches the claimed invention. Therefore, Belardelli et al. anticipates the claimed invention.

It is noted that the claims require the composition to expands in vivo expression of virus-specific CD8+ T cells, and said virus-specific CD8+ cells kill HIV-infected cells; however, MPEP § 2112 [R-3] (I) provides: [T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999).

¹ Belardelli et al. U.S. PreGrant Patent No. 2003/0092177 A1, filed April 27, 2001.

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Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In *re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." *Id.*

In the instant case, while it may be true that Applicant discovers that the claimed composition expands *in vivo* expression of virus-specific CD8+ T cells, and said virus-specific CD8+ cells kill HIV-infected cells; however, this discovery does not make the composition patentable over the composition of Belardelli et al. Belardelli et al. teaches a composition that is the same as instantly claimed. The composition of Belardelli et al. is the claimed composition. Hence, Belardelli et al. does not need to teach that the composition expands *in vivo* expression of virus-specific CD8+ T cells, and said virus-specific CD8+ cells kill HIV-infected cells to anticipate the claimed invention. The composition of Belardelli et al. would have the same properties or functions recognized by Applicant.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Belardelli et al., as applied above to claim 43.

Claim 44 is directed to the composition of claim 43, however, further requires that the virus be autologous.

The significance of Belardelli et al., as applied to claim 43, is provided above.

While the dendritic cells used by Belardelli et al. are autologous, it is not readily apparent if the virus used by Belardelli et al. is also autologous. It should be noted that Belardelli et al. uses the cells as an adjuvant, and the inactivated virus as an immunogen/antigen.

However, due to the many variability in the many type of HIV isolates and the ability of the virus to mutate, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was made, to use autologous HIV. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to induce an immune response against the specific HIV isolate infecting the subject. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the use of autologous antigens is routinely practiced in the art.

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7. Claims 52-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belardelli et al., as applied above to claim 43, in view of Lu et al.²

The claims require the composition to further comprise an adjuvant. The adjuvant is later limited to a protease inhibitor by claim 53, which depends on claim 52. The protease inhibitor is later limited indinavir by claim 54, which depends on claim 53. Claim 55, which depends on claim 54, later requires that the composition comprise a non-antiviral concentration of indinavir. And claim 56 limits the non-antiviral concentration to 10 nM.

The significance of Belardelli et al., as applied to claim 43, is provided above.

The composition of Belardelli et al. does not further comprise indinavir. However, Lu et al. teaches that indinavir direct up-regulate proliferation and down regulate apoptosis of T cells. [Paragraph bridging pages 247-248.]

Thus, would have been prima facie obvious for one of ordinary skill in the art to combine the teachings of Belardelli et al. and Lu et al. One of ordinary skill in the art would have been motivated to do so to optimize CTL response against HIV infection. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because the determination of a workable or optimal range is routinely practiced in the art.

It is recognized that claims require the composition to contain non-antiviral concentration of indinavir, specifically 10 nM. In the instant, Lu et al. teaches that the extent in which indinavir up-regulate proliferation and down regulate apoptosis of T cells

² Lu et al. HIV protease inhibitors restore impaired T-cell proliferative response in vivo and in vitro: a viral-suppression-independent mechanism. Blood, Jul 2000; Vol. 96, 250 - 258.

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varies at different concentrations of indinavir. Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use any concentrations of indinavir, particularly since Lu et al. establishes that indinavir at various concentrations, ranging from .1nM to 1000 nM, stimulates direct up-regulate proliferation and down regulate apoptosis of T cells. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to determine the optimum concentration to optimize the proliferation of T cells. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because the determination of workable ranges or optimal value is routine practiced in the art.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164

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USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 43-44, 46 and 52-56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/138171 in view of Belardelli et al. and Lu et al.

In response to this rejection, Applicant notes that Applicant will address this rejection upon allowance of claims 43-44, 46 and 52-56.

Applicant's submission has been noted. Until the rejection is properly addressed, the rejection is maintained.

This is a provisional obviousness-type double patenting rejection.

10. Claims 43-44, 46 and 52-56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 7 and 13 of copending Application No. 11/243094 in view of Belardelli et al. and Lu et al.

In response to this rejection, Applicant notes that Applicant will address this rejection upon allowance of claims 43-44, 46 and 52-56.

This is a provisional obviousness-type double patenting rejection.

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily M. Le/
Patent Examiner
Art Unit 1648

/E.Le/